TENT COOPERATION TREA Y

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 21 December 1998 (21.12.98)	
International application No. PCT/US98/03197	**Applicant's or agent's file reference** CRP-144PC
International filing date (day/month/year) 05 May 1998 (05.05.98)	**Priority date** (day/month/year) 05 May 1997 (05.05.97)
Applicant SAMPATH, Kuber, T. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

03 December 1998 (03.12.98)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

N. Masson

Telephone No.: (41-22) 338.83.38

-19

PATENT COOPERATION TREATY

RECD 30 JUL 1999
WIPO PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
CRP-144PC		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US98/03197	05/05/1998	05/05/1997
International Patent Classification (IPC) or national classification and IPC A61K38/18		
Applicant CREATIVE BIOMOLECULES, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03/12/1998	29.07.99
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. (+49-89) 2399-0 Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Brunnauer, H Telephone No. (+49-89) 2399 8338

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US98/03197

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-20 as originally filed

Claims, No.:

1-52 as originally filed

Drawings, sheets:

1-26 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2, 15-18, 20-21, 23-24, 29-33, 40
	No:	Claims	1, 3-14, 19, 22, 25-28, 34-39, 41-52
Inventive step (IS)	Yes:	Claims	----------
	No:	Claims	1-52
Industrial applicability (IA)	Yes:	Claims	1-52 (see section V. 4.)
	No:	Claims	----------

2. Citations and explanations

see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Section V

1. Reference is made to the following documents:

   D1: Journal of the American Society of Nephrology, vol. 7, no. 9, page 1867, 1996
   D2: WO 93 05751 A
   D3: WO 93 04692
   D4: WO 94 03200 A

2. Novelty according to Article 33(2) PCT

2.1 The examination with respect to novelty was performed under the following presumptions:
The term "..renal therapeutic agent.." in claims 1-7, 13-14, 37-45 and 51-52 is not regarded as being a distinguishing feature, since the substances are already known in therapy. This term does not further characterize claimed additional medical uses.

Claims 1-4 and 39-42 are interpreted in the sense, that the polypeptides selected represent either the group consisting of OP or BMP, by using the term "..OP/BMP.." .

2.2 Document D1 (abstract) refers to a preclinical trial with nephrectomized rats and the study of the effect of systemically applied OP-1/BMP-7, a member of the TGF-beta subfamily, upon delay or halt progression of end stage renal failure. Recombinant human OP-1 at doses of 1, 10 and 100 µg / kg were administered 3 times per week intravenously beginning 3 weeks after surgery and continued for 10 to 24 weeks. The results show that 10 or 100 µg / kg treated groups significantly decreases the elevated serum blood urea nitrogen (BUN) and creatinine values from 2 weeks after the initiation of OP-1 therapy.
Histological evaluation of kidney tissue sections showed cytoprotection against glomerular sclerosis and there were also evidence of preservation of proximal and distal tubular structures. The authors suggest, that OP-1 may play a role in cell survival and tissue morphogenesis and, as such, may provide a basis for the treatment of chronic renal disease.

These disclosures are novelty destroying to claims 1, 4, 5, 6, 13, 14,19, 22, 26, 27, 35-38 and 39, 42-44 and 51.

Document D3 (claims 1, 24, 26-29 on page 145-147) relates to a method for alleviating and protecting the inflammatory response induced in a mammal following tissue injury, including the renal tissue, by means of administering morphogens, recruited i.a. from OP-1, OP-2, BMP3, BMP5 and BMP6, or morphogens which comprise an amino acid sequence having greater than 60% or 65% amino acid identity or at least 70% or 80% homology with one of the sequences as selected from the above mentioned morphogens.
Examples 11, 12 and 14 (page 88-89; 92) refer to specific inhibitory effects of said morphogens in inflammatory response. Said morphogens may be provided to an individual by any suitable means, i.a. by the oral or parenteral (intravenous, intraperitoneal) route (page 51, line 4-9).
These disclosures take the novelty of claims 3, 5-12, 14, 25-28, 41, 43-50 and 52.

Document D4 (page 8, line 4-17) is directed to the use of morphogens for maintaining neural pathways in a mammal, including the enhancement of the survival of neuronal cells. Said morphogens are suitable to repair said pathway or to inhibit additional damage thereto.
Said morphogen is preferably provided to the site of application (page 10, line 18-20). Further on, said agents are useful for providing neuroprotective effects to alleviate neural pathway damage associated with the body`s immune/inflammatory response to an initial injury to nerve tissue (page 14, line 15-19).
Said morphogen comprises an amino acid sequence sharing at least 70 % homology (claim 23, page 157) or 80% homology (claim 24, page 157) with one of the sequences selected from the group of i.a. from OP-1. Said morphogens can also comprise an amino acid sequence having greater than 60% (claim 25, page 158) or 65% (claim 26, page 158) amino acid identity with the sequence defined by OP-1.
These disclosures anticipate subject-matter of claims 3-12, 14, 34, 41- 50 and 52.

Claims 2, 15-18, 20-21, 23-24, 29-33 and 40 are regarded as being novel, since none of the prior art documents discloses corresponding, particular subject-

matter.

3. Inventive step according to Article 33(3) PCT

Document D1 differs from claims 2, 15-18, 20-21, 23-24, 29-33 and 40 of the application in that:

1) said OP/BMP agent is not disclosed as being useful in delaying the need of dialysis or reducing the frequency of dialysis (claims 2, 40),
2) said renal disease is not further characterized by the increased rate of BUN or serum creatinine (claims 15-18),
3) said renal failure is due to an intrinsic renal cause but not to a pre-renal- (claim 20) or post-renal- (claim 21) cause,
4) said renal patient has not received a kidney transplant (claim 23) or possesses only one kidney (claim 24),
5) said method of administration does not in particular refer to the application into the renal capsule (claim 29) or by means of a stent (claims 31-33),

In view of D1, the objective technical problem of the application is to find further renal applications for the known morphogens as well as suitable routes of administration.

Claims 2, 40, 20-21 and 23-24

The solution according to claims 2, 40, 20-21 and 23-24 of the application is to use said agents also for treating dialysis patients or patients suffering from renal diseases caused by pre- or post- renal disturbances or treating particular patients with only one kidney or which are transplant recipients.

The proposed solution is however not inventive, because it is already known from document D1, that said OP-1 shows a cytoprotective effect in the kidneys, resulting in the preservation of renal structures. Further on, the authors suggest that said OP-1 may also provide a basis for the treatment of chronic renal disease. From this teaching, the person skilled in the art would be obviously led to consider not only the therapy of acute renal failure with said morphogen, but also chronic disease states, like dialysis, or particular disease states in the context with

patients having only one kidney available or kidney recipient patients. These patients are characterized by an increased need for renal cytoprotection. Document D1 already suggests such a cytoprotection by means of administering the morphogen OP-1.

Further on, document D2 suggests the use of said agents in the treatment of chronic renal diseases:
Document D2 (abstract; page 12, 15-16) is directed to the treatment of bone diseases by means of administering to a patient a suitable morphogen, i.a. OP-1, OP-2, BMP-3, BMP-4, BMP-5 and BMP-6, which increases the bone mass or prevents bone loss. It is referred to said agents as being useful in the treatment of any other disease which causes or results in skeletal defects, including i.e. chronic renal failure and other kidney diseases, particularly those requiring dialysis (page 8, line 25-31 and claim 47, page 147).

Claims 15-18
The further characterisation of said renal diseases by means of defining the increased rate of Bun- or serum creatinine levels is not regarded as involving an inventive step, since the skilled artisan would be led by the teaching of D1 to treat any disease state of renal failure or renal conditions affording dialysis, independently of the degree of severity.

Claims 29-33
Subject matter of claims 29-33 does equally not involve an inventive step, as the different modes of administration are considered as obvious modifications. Document D2, for instance, suggests already the administration of said morphogens (page 49, line 1) by means of a directly, i.e. locally, application. With this respect, D2 refers to i.a. the subcutaneously implantation of OP-1 in a mammal, which resulted in an induced endochondral bone formation (page 51, line 10-12).
The use of stents according to claims 31-33 is not regarded as inventive, since the skilled person would consider this kind of administration also alternatively.

4. For the assessment of the present claims 1-52 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can

also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Section VI

Following patent applications, classified as x, p-documents in the international search report, are cited:

WO 97 41880 A, published 13 November 1997, filed 6 May 1997 with the priority date of 6 May 1996 and
WO 97 41881 A, published 13 November 1997, filed 6 May 1997 with the priority date of 6 May 1996.

Section VII

Contrary to the requirements of rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
CRP-144PC		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 98/ 03197	05/05/1998	05/05/1997

Applicant

CREATIVE BIOMOLECULES, INC. et al.

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [X] **Certain claims were found unsearchable** (see Box I).

2. [ ] **Unity of invention is lacking** (see Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] Transcribed by this Authority

4. With regard to the **title,**
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:
   Figure No. _____
   - [ ] as suggested by the applicant.
   - [ ] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.

   [X] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/03197

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 1 - 38 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/03197

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K38/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	VUKICEVIC ET AL.: "Recombinant human OP-1 (BMP-7) prevents rapid loss of glomerular function and improves mortality associated with chronic renal failure" JOURNAL OF THE AMERICAN SOCIETY OF NEPHROLOGY, vol. 7, no. 9, 1996, Nov 3-6 page 1867 XP002038677 see abstract no. A3102 ---	39,40, 43-52
X	WO 93 05751 A (CREATIVE BIOMOLECULES, INC.) 1 April 1993 see page 8, line 23 - line 31 see page 11, line 6 - line 19 see claims 45-52 --- -/--	39,40, 43-52

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 August 1998	

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Alvarez Alvarez, C

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 04692 A (CREATIVE BIOMOLECULES, INC.) 18 March 1993 see claims 1,24,26-30,56; examples 5,11,12,14	41,43-52
X	WO 94 03200 A (CREATIVE BIOMOLECULES, INC.) 17 February 1994 see page 12, line 20 - page 13, line 18 see claims 1,2,23-27	42-52
X,P	WO 97 41880 A (CREATIVE BIOMOLECULES, INC.) 13 November 1997 see the whole document	39,40, 43-52
X,P	WO 97 41881 A (CREATIVE BIOMOLECULES, INC.) 13 November 1997 see claims 1,8,50-56	39,40, 43-52

INTERNATIONAL SEARCH REPORT

International Application No

rmation on patent family members

CT/US 98/03197

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/03197

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU 2933997 A	26-11-1997
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